K061722

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	CrossLink-D, Inc. 3480 Industrial Blvd. Ste. 105 West Sacramento, CA 95691
CONTACT PERSON	Louis J. Mazzarese Consultant to CrossLink-D, Inc.
DATE PREPARED	August 1, 2006
CLASSIFICATION	Dressing; FRO Class: Unclassified
COMMON NAME	Surgical bandage
PROPRIETARY NAME	Bloxx™ Rapid Clotting Agent
PREDICATE DEVICE	Traumadex™/Bleed-X™ containing Hemadex™ Clotting Beads Medafor, Inc. (Minneapolis, MN) K013225 (Dec. 26, 2001)
DEVICE DESCRIPTION	Bloxx™ Rapid Clotting Agent is a hemostatic gauze pad treated with cross-linked dextran for the purpose of promoting rapid hemostasis.
TESTING	Laboratory and animal testing using rabbit and porcine models confirms the safety and efficacy of Bloxx™ Rapid Clotting Agent for the local management of bleeding wounds.
INDICATIONS FOR USE	Bloxx™ Rapid Clotting Agent is a hemostatic gauze pad intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for the temporary treatment of severely bleeding wounds such as surgical wounds (operative, post operative, donor sites, dermatological, etc.), and traumatic injuries.

AUG 0 2 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

CrossLink-D, Inc.
% Mr. Louis J. Mazzarese
150 Aran Hill Road
Fairfield, Connecticut 06824-1712

Re: K061722
Trade/Device Name: Bloxx™ Rapid Clotting Agent
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 15, 2006
Received: June 19, 2006

Dear Mr. Mazzarese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510(k) Number: K061722

Device Name: **Bloxx™ Rapid Clotting Agent**

Indications for Use:

Bloxx™ Rapid Clotting Agent is a hemostatic gauze pad intended for use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions.

It may also be used for the temporary treatment of severely bleeding wounds such as surgical wounds (operative, post operative, donor sites, dermatological, etc.), and traumatic injuries.

Prescription Use: Yes

DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061722